

PROVISIONAL APPLICATION STATEMENT

This applications claims the benefit of the filing date of Provisional Patent Application.

Number 60/274,206 Filing Date 03/09/2001 Title: SafeRite SystemTM

SafeRite SystemTM

BACKGROUND OF INVENTION

Medical errors have recently been attributed as a leading cause of death and injury in North America. Many of these medical errors relate to prescription drug mix-ups, such as the patient receiving the wrong drug, or the wrong strength of the right drug etc. Some of these errors are attributed to physician's illegible handwriting, and others to drug selection and dispensing errors in the pharmacy. Other errors result when the drug is administered to the wrong patient in hospital

In response to the issue of sloppy handwriting by physicians some products 9, 10 are coming to market that print an Rx. Generally speaking, these prescriptions are "written" in the physician's office and entail the use of a PDA, (or handheld computer etc.) PC, and office printer.

Although these technologies print a clearly legible Rx 9, 10 – in either hard copy or electronically sent format – they lack design components 3 that prevent pharmacy selection errors. Nor do they provide the patient the means to determine the dispensed drug matches their prescription

THE 3 PART ACTION PLAN TM

In order to prevent medication errors, the following three actions must occur:

- Prevent errors that originate with the physician/writer
- Prevent pharmacy dispensing errors
- Involve the patient

Failure to adopt any one of these actions will result in the ongoing – and unabated – flow of medication errors.

FIG 11

Vendors of Hand-held Electronic Prescribing Products

COMPANY	NO. PHYSICIAN USERS*	HEADQUARTERS	WEB ADDRESS
Allscripts, Inc.	12,000 (2000)	Libertyville, IL	www.allscripts.com
Autros Healthcare Solutions	**	Toronto, Canada	www.autros.com
Ephysician	4,500 (2000)	Mountain View, CA	www.ephysician.com
Iscribe	***	San Mateo, CA	www.iscribe.com
Notre	>100	Philadelphia, PA	www.notre.net
ParkStone Medical Information Systems	>300	Fort Lauderdale, FL	www.parkstonemed.com

* As of 12/31/99

** In-patient application only: no U.S. installations yet

*** Scheduled for release in 2000

An examination of the PDA/R_x products listed above has found all are uniform in their design approach.* Each R_x met the criteria of part one of the 3 Part Action Plan – that is, the R_x's were checked and printed in the physicians office (or sent to the pharmacy electronically) – but lacked the design features necessary to provide other stakeholders in the R_x loop (the pharmacist, nurse and patient) a comprehensive R_x safety platform. Other than providing a legible (printed) R_x to the pharmacist, competing products did not meet the criteria set out in Part Two or Part Three of the 3 Part Action Plan and therefore do nothing to prevent errors occurring in these areas.

*Autros is a hospital system, designed to deliver dispensed drugs to patients in the ward - but lacks the capabilities of the SafeRite System to prevent drug mix-ups in the hospital pharmacy. Therefore, Autros cannot guarantee the prescribed drug reaches the patient.

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HOW AND WHY THEY HAPPEN

Medication errors can be divided into two main categories and occur when:

Prescriptions are Written	Prescriptions are Dispensed
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The following errors occur at the time the prescription is written:

- Wrong Drug
 - The selected drug is inappropriate for the patient's medical condition
- Strength
 - The correct drug – but wrong strength
- Instructions
 - The correct drug – but wrong dosage instructions
- Abbreviation
 - The incorrect use of an abbreviation
- Interaction
 - The prescribed drug will interact with (other) current R_x 's
- Contraindication
 - Drug not compatible with patients medical condition
- Allergy
 - The patient is allergic to the drug
- Patient's name
 - The wrong patient name is written – sometimes the name of the previous patient
- Verbal Orders
 - Orders given by telephone are a continuing source of errors
- Handwriting
 - The physicians handwriting is illegible or difficult to read

PHARMACY DISPENSING ERRORS

The following errors occur at the time that the pharmacist fills the prescription.

- Handwriting - Illegible - or difficult to read - handwritten prescriptions lead to many dispensing errors
- Verbal Orders - Orders received by telephone are often misunderstood.
- Drug Selection - The wrong drug is selected
- Look Alike - Selection errors occur when drug names look alike
- Sound Alike - Selection errors occur because drug names sound alike
- Strength - The wrong drug strength is selected
- Instructions - Incorrect patient instructions
- Interaction - The dispensed drug will interact with (other) current R_x's
- Contraindication - Drug not compatible with patients medical condition
- Allergy - The patient is allergic to the drug
- Patient Chart - Various entry errors and chart mix-ups
- Communication - The R_x is given out to the wrong patient
- DIN Number - Drug DIN number is confused with look alike DIN number

IN THE HOSPITAL

Hospital medication errors are divided into three main categories and occur when:

Prescriptions are Written	Prescriptions are Dispensed	Prescriptions are Administered
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In addition to the same prescribing and dispensing errors high-lighted under Ambulatory Care, further medication errors occur in the hospital when patient identities are confused, resulting in drug mix-ups (the patient is given someone else's medication).

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BRIEF SUMMARY OF THE INVENTION

THE SAFERITE SYSTEM™

The SafeRite System™ provides a state of the art, user friendly, low cost solution to the widespread problem of drug mix-ups. The System enables an error free Rx to progress seamlessly from the physician through the pharmacy to the patient. The System's design is unique and is the only Rx technology to address each of the 3 error prevention criteria outlined in the 3 Part Action Plan (competing products address 1 only).9,10

COMPARING THE EFFICACY OF PDA GENERATED Rx's

FIG. 12

PREVENTING MEDICATION ERRORS IN THE AMBULATORY CARE SETTING		
ERROR PREVENTION BENEFITS	SAFERITE SYSTEM	ALL COMPETITORS *
PHYSICIANS OFFICE	YES	YES
PHARMACY	YES	NO
PATIENT INVOLVEMENT	YES	NO
IN THE HOSPITAL		
ERROR PREVENTION BENEFITS	YES **	(AUTROS ** ONLY)
* BASED ON THE LIST OF VENDORS OF HANDHELD ELECTRONIC PRESCRIBING PRODUCTS (SEE FIG. 11)		
** SIGNIFICANT TECHNOLOGY AND COST DIFFERENCES		

The SafeRite System's™ Rx technology incorporates safety features that are unavailable to its competitors.

The SafeRite System™ consist of two sub-systems:

1. SafeRite™ is the hardware/software system used by the physician to ‘write’, bar code and print – or electronically transmit – the two part R_x.
2. SafeReader™ is the hardware/software bar code scanning system used by the pharmacist to prevent drug mix-ups in the pharmacy.

HOSPITAL SYSTEM

In addition to the benefits of SafeRite and SafeReader outlined above the hospital system includes a bedside visual display that enables the nurse to determine that the prescribed drug goes to the correct patient.

FULLY INTEGRATED

SafeRite's™ bar coded R_x is fully integrated with SafeReader's™ comparative scanning mechanism – resulting in a unique and highly efficient, error prevention system.

- SafeRite assists the physician to quickly and accurately ‘write’ and print a prescription. By using a printed prescription format, the SafeRite System™ precludes errors associated with illegible handwriting.
- SafeRite prints a bar code – representing the drug's name and strength – on the R_x.
- SafeReader's innovative design enables the pharmacist to quickly carry out a bar code comparison check of the R_x and drug selected from stock. This crucial step prevents pharmacy selection errors.
- Finally, the Patient Checklist portion of the R_x encourages patient participation in the prescription loop by providing the patient an easy to follow sequenced checklist.

- Safety features – incorporated into the R_x – are available at each crucial [decision making] juncture of the R_x loop.
- The efficiencies provided to physicians by the SafeRite System™ will discourage giving verbal R_x orders by telephone.
- The SafeRite™ R_x will conform to all federal and state/provincial requirements.
- Competing R_x products offer a printed R_x, but do not incorporate a bar code (pharmacy protection) or patient checklist, nor do they offer a visual check for hospital use.

The SafeRite System™ provides end users with a powerful safety technology. Benefits accruing to the end user and health care system are substantial financial paybacks resulting in the cessation of deaths and injuries to patients, together with the professional satisfaction of providing the patient a risk free (medication) environment.

DRAWINGS

- FIG 1 Illustration showing the two part SafeRite R_x.
- FIG 2 Schematic showing sequence of SafeRite R_x and 3 Part Action Plan
- FIG 3 Illustration showing a SafeRite generated R_x in which a Generic substitution takes place. The green bordered label is affixed to Box Four.
- FIG 4 Illustration of Green bordered generic label see FIG. 3
- FIG 5 Illustration of bar coded label. Label is attached to any [non-SafeRite] R_x. For example: to the reverse side of R_x's shown in FIGS 8 and 9
- FIG 6 Schematic of SafeRite/SafeReader sequence of use in Hospital and Clinical settings.
- FIG 7 Illustrated bedside visual display for Hospital and Clinical use.
- FIG 8 Schematic showing carry case for printer and PDA
- FIG 9, 10 R_x samples of competitive computer generated R_x products.
- FIG 11 Chart showing Vendors of Hand-held Electronic Prescribing Products
- FIG 12 Chart comparing efficacy of PDA generated R_x's.

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DETAILED DESCRIPTION OF INVENTION

The SafeRite System™ consist of two sub-systems:

1. SafeRite™ is the hardware/software system used by the physician to ‘write’, bar code and print – or electronically transmit – the two part R_x. FIG 1, 11
2. SafeReader™ is the hardware/software bar code scanning system used by the pharmacist to prevent drug mix-ups in the pharmacy. 12

HOSPITAL SYSTEM

In addition to the benefits of SafeRite and SafeReader outlined above, the Hospital System FIG.6 includes a bedside visual display (BVD)17 that enables the nurse to determine that the prescribed drug is administered to the correct patient.

THE SAFERITE R_x

PRESCRIPTION DESIGN

The design of the SafeRite™ R_x involved meeting the following four part criteria:

1. Produce a computer generated (printed) R_x FIG 1
2. Build in safety features and increase content 2, 3, 4
3. * Involve the patient in a final cross-check of the dispensed drug 4
4. Provide a user-friendly system, requiring minimum R_x input

* Note: As part of a discussion on how to prevent drug mix-ups – “and make the patient their own best defense” – Michael Cohen, of the ISMP, states: “I think it’s becoming very, very important, for the consumers to be informed about what their medications are for, what the names are, how to take them and what the doses are.” 4

The patient's portion of the SafeRite™ prescription leads the patient through the easy to follow Patient Checklist. 4

R_x FEATURES

- Clear, large, easy to read printed R_x 2, 4
- Bar coded – for pharmacy use 3
- Unique two part design – includes patient checklist 2, 4
- Flexible format – print and/or electronic transmission 11
- Conforms to the “3 Part Action Plan” 2, 3, 4

BRAND NAME / GENERICS

To prevent generic substitution, the physician must write the appropriate state/provincial statement requirement i.e. *No Substitution* 5 or *Dispense as Written* etc. in the box provided.

PREVENTING LOOK ALIKE / SOUND ALIKE ERRORS

A simple, effective, low cost method of preventing “look alike/sound alike” medication errors - and other selection errors - while filling the Rx in the pharmacy 12, is by incorporating a bar code – containing the drug's brand name and strength – into the Pharmacist's Print Out portion of the R_x. 3 The R_x bar code duplicates the drug's brand name and strength, contained in the bar code appearing on the drug's stock container.

To determine the drug taken from stock matches the R_x, the pharmacist scans the bar codes appearing on both the R_x and the drug's stock container 12, an incorrect selection – of the drug or drug strength – is immediately flagged:

Note: Scanning is accomplished by using a handheld scanner or a dedicated scanning unit. The unit facilitates the check by scanning both bar codes more or less simultaneously. The unit's program accepts matching codes, but rejects (flags) non-matching codes. The pharmacist rectifies an error by selecting the correct drug/stock container. Matching bar codes allow the program sequence to continue.

HOW MANY TABLETS A DAY?

The R_x instruction – take 1 tablet daily with meals – can be thoroughly confusing to some patients. Do they take 1 tablet each day OR 1 tablet with each meal? To remedy this common misunderstanding, an information block is added to the bottom of the Patient's Checklist.

For example, the R_x for Zoloft – take 1 capsule daily with meals – would read: 7

Total number of capsules taken daily = 1
--

The R_x for Flagyl – take 2 tablets 3 times a day with meals – would read:

Total number of tablets taken daily = 6

While the R_x for Tylenol 3 – take 1 to 2 tablets 4 times a day as needed – would show the daily maximum allowable dosage:

Do not exceed 8 tablets daily

SYSTEM REQUIREMENTS

PHYSICIAN'S OFFICE (Part One) SAFERITE™ 11

HARDWARE

- PDA – MODEM – CRADLE
- PC
- PRINTER

Note: PDA can mean any type of computer. The prescriber can also use the office PC to “write” the R_x.

The PDA communicates with the PC and printer by wireless transmission (or infrared).

SOFTWARE

- Prescription software for PDA and PC
- PDA/PC interface software

SEQUENCE OF USE

The physician calls up the patient's name/file, from the office PC, on their PDA. 11

- Using their PDA the physician enters the reason for treatment – ie depression 10 – and is given a menu of appropriate drugs, then electronically “writes” the prescription by selecting drug, dosage, quantity, and patient instructions 2
- The program checks that the selected drug is correct for the patient's medical condition, contraindications, for drug interactions with other current prescriptions and for correct patient instructions. Allergies are flagged
- Check patients health plan formulary for drug approval

- A bar code representing the drug brand name and strength is transferred to the R_x 3
- The physician then reviews R_x, prints and signs (if sending by computer fax etc – the signature is computer generated)
- To print: the PDA communicates wirelessly with the printer 11, 12
- To send to the pharmacy: the PDA sends the R_x to the PC. The PC electronically sends the R_x directly to the pharmacy via the Internet over a secured line. (Electronic R_x transmissions are permitted in most states, and will be soon allowed in Canada.)
- By using their PDA with WAN (wireless wide area network) capability, the physician is able to transmit, or fax an R_x to a pharmacy from remote locations
- The transmitted data is encrypted, complying with patient confidentiality issues
- To facilitate refills: the physician uses their PDA to call up the patients' file

HIGHLIGHTS

- Access to patient's file
- Printed R_x – prevents pharmacy errors caused by poor handwriting. Eliminates time consuming calls from pharmacists. Some physicians report saving 1 – 2 hours daily when using similar products
- Undertakes complete check of the R_x data
- Flags allergies
- Checks health plan formulary for drug authorization
- Choice of R_x format – printed in the physician's office and/or electronically sent to the pharmacy
- The R_x data is transferred to the patient file on office PC

- Speeds up the refill process. R_x data from patient file instantly available on PDA
- Prevents patient morbidity and mortality events
- Reduces the chance of lawsuits
- Reduces malpractice insurance premiums
- Drug safety notices etc, flagged on the physicians office computer, are transferred to the SafeRite System – continually upgrading the System's software
- Conforms to the 1st part of the "3 Part Action Plan" 2

IN THE PHARMACY (Part Two) *SafeReaderTM*

HARDWARE

- SafeReaderTM (combination bar code reader/printer) 12 provides an automated bar code comparison scan of the R_x 3 and drug's stock container. Prints Box four illustrated generic data 14
- SafeReaderTM an indispensable pharmacy tool, which guarantees the drug taken from stock matches the R_x 3 in both selection and strength 12

SOFTWARE

- Compares R_x bar code 3 with bar code displayed on drug stock container 12
- Accepts generic substitutes to brand name drugs
- Transfers – Brand Name or Generic – scanned stock container's bar code to pharmacy working copy and patient R_x file

SEQUENCE OF USE

- Brand Name drug selection: To determine the drug taken from stock matches the R_x, the pharmacist places both the R_x and the drug stock container on the SafeReader™ unit 12
- SafeReader™ quickly performs a dual bar code scan – comparing drug name(s) and strength(s). Non matching data is immediately flagged 12
- SafeReader™ prints a validation (check) mark on the R_x 9. The pharmacist subsequently places his/her initials in the box provided 8
- SafeReader™ then transfers the drug's bar code to the pharmacy working copy and patient R_x file
- The Brand Name drug's bar code acts as a master bar code, and matches all generic substitute bar codes 3
- Generic drug selection: the generics' stock container is placed on SafeReader™ 12 and the generic container's bar code is scanned against the R_x's 3 bar code. SafeReader™ then transfers that [specific] generic drug's bar code* to the pharmacy working copy and patient's R_x file. SafeReader prints a new Box Four information – containing the generic drug's data and illustration – onto an adhesive sticker, 15 which the pharmacist places over the original Box Four 6,14 (containing Brand Name drug data) on the Patient Checklist.
- On refills, the drug's [specific] bar code – from the patients' R_x file – is transferred to the pharmacy working copy
- The bar coded working copy is placed on SafeReader™ 12 – in the same manner as the original R_x 3 – and scanned against the drug's stock container – preventing refill mix-ups

* The bar codes of allowable generic substitutions [to a given Brand Name drug] are not interchangeable. Only the originally dispensed generic drug's bar code will subsequently be accepted by SafeReader, thereby preventing mix-ups of [allowable] generic drugs when refilling an order.

At the time the generics' bar code is transferred to the pharmacy working copy and patient R_x file, the Brand Name's bar code data – imprinted on the R_x – is automatically invalidated by SafeReader, thereby, isolating the generics' [specific] bar code for future scanning checks.

Likewise, when a Brand Name drug is to be filled – and its bar code data transferred from the R_x to the pharmacy working copy and patient R_x File – the allowable generic substitution information – contained in the Brand Name's master bar code – is invalidated by SafeReader. Therefore, only SafeReader, assuring correct drug selection recognizes the bar code belonging to the Brand Name drug.

ADDITIONAL R_x BAR CODE(S)

Another bar code – containing patient ID etc. is added to the R_x – when scanned by SafeReader, this bar code opens up the (pharmacy) patient R_x file, preventing patient chart mix-ups and R_x/patient entry errors. This feature will facilitate further [scanned] safety checks. Other bar codes are added as necessary.

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GENERIC EQUIVALENT - ATTACHMENT

SAFEREADER™ II – AN INTERMEDIATE SOLUTION

SafeReader™ II's software program, in essence, is the drug selection/bar coding portion of the physicians SafeRite™ software program. SafeReader™ II equips the pharmacist with a powerful safety tool. SafeReader™ II's program converts any R_x to a SafeRite™ [bar coded] type R_x. To accomplish this, the pharmacist enters the R_x drug name and strength into the pharmacy computer – the [SafeRite II] program converts this data to a bar code, which is printed together with drug name and strength, on an adhesive sticker 16, and affixed to the R_x. The bar coded R_x [attachment] and drug stock container are subsequently scanned by SafeReader™ 12 to assure correct drug and strength selection. The program then prints an abbreviated, illustrated Patient Checklist which accompanies the dispensed drug. 4

On the other hand, pharmacists who receive a SafeRite™ R_x 2, in a non SafeReader™ pharmacy, will benefit from SafeRite's™ printed R_x and Patient Check- List. 4

PRINTING OPTIONS

The primary function of SafeReader™ is to provide a comparative bar code scan of the bar codes appearing on the R_x 3 and drug stock container. Printing is accomplished by incorporating a printer together with the bar code scanning mechanism into a single, stand-alone unit, or the printer is connected to the SafeReader unit.. The printer is calibrated to print a generic attachment 14 that affixes to Box Four of the Patient Check-List. Alternatively SafeReader™ functions solely as a bar code scanner, and the pharmacy printer undertakes printing the Box Four generic attachment. 14

The pharmacist, together with the patient, goes through the patient Checklist. 4

- Easy to read, printed R_x – prevents errors caused by poor handwriting – eliminates the need to call physician for clarification 2
- Eliminates the need to call physician regarding missing R_x data : (ie quantity) 2
- An infallible method of preventing drug selection errors 3
- Patient diagnosis 10 prominently displayed on R_x- enables pharmacist to determine that the prescribed drug matches the patient's medical condition.(The MD may omit this information)
- Facilitates refills – scans [bar-coded] working copy with [bar coded] stock container.
Prevents refill drug mix-ups
- Prevents patient morbidity and mortality events
- Reduces the chance of lawsuits
- Reduce malpractice premiums
- Conforms to the 2nd part of the “3 Part Action Plan” 3

The patient is the ultimate beneficiary of the SafeRite System™. Each feature of the Systems' technology is designed to prevent patient injury and death caused by medication errors. In doing so, the System confers many benefits to the other stakeholders in the R_x loop: namely the physician 2, pharmacist 3, and nurse. 17

HARD COPY

- Patient Print- Out portion of the R_x (Patient Checklist) 4
- The Patient's Checklist accompanies the dispensed R_x

SEQUENCE OF USE

- On receiving the dispensed drug, the patient – together with the pharmacist – follows the Checklist to compare the Patient Checklist data with the information printed on the prescription vial/container. 4
- Finally, the patient and pharmacist visually check that the dispensed medication matches the drug illustration in Box Four of the Checklist 6. In many cases the illustration is life-size.
- This third and last step of the 3 Part Action Plan – which takes only a few moments – is critical to the success of the error prevention program, and at the same time, conforms to [pharmacy] professional patient counseling requirements.

HIGHLIGHTS

- Patient receives correct drug
- The System accesses pharmaceutical companies offering no cost/low cost drugs to patients encountering financial hardship.
- The patient is involved in a crucial step of the R_x loop
- Is guided through the checklist sequence 4
- Conforms to and completes all actions in the “3 Part Action Plan” 4
- Reduces patient morbidity and mortality events.

IN THE HOSPITAL

HARDWARE:

- PDA
- Printer
- SafeReader™
- Bedside Visual Display Kit 17

The hospital system requirements are much the same as those for the physician and pharmacy.

SEQUENCE OF USE 16

- Doctor makes rounds, then using SafeRite™
- Selects and prints R_x. The R_x is either printed at the patient's bedside by using a handheld printer, or at the nurse's station (Drs. Desk)
- Copy of Patient Checklist (hospital version) placed in Bedside Visual Display 17 (BVD) *
- 2nd copy of R_x and Patient Checklist placed in Patient Drug File (PDF) at nurses' station.*
- The doctor transmits the R_x to the hospital pharmacy by fax, LAN or WAN - or submits a printed copy
- R_x data subsequently downloaded to patient's file on physician's office PC

* When a generic substitution of the prescribed drug has taken place, the nurse attaches copies of the illustrated generic attachment 14 to Box Four of the Patient Checklist of the BVD 17 and PDF. Generic attachments are printed once only, and accompany the drug the first time it is dispensed to the patient.

HIGHLIGHTS

In addition to:

- Physician Highlights
- Pharmacy Highlights
- Patient Highlights

Additional Hospital Highlights:

- Writing and printing the R_x at the patients bedside
- Patient Drug File (PDF). Enables check of R_x received at Nursing Station
- Bedside Visual Display 17 (BVD). Provides nurse with illustrated R_x information
- Infallible and inexpensive method of administering the right drug to the right patient

IN THE HOSPITAL PHARMACY

- The pharmacist scans the R_x and drug stock container 12 – assuring correct drug and strength selection, prints generic sticker 14 – when necessary – and includes them with the patients drug. (Alternatively, a copy of the Patient Checklist accompanies the R_x, in which case, the pharmacist attaches the generic sticker 14 to Box Four of the Checklist, in the usual fashion (and an extra one for the PDF). The nurse peels off one of the stickers, attaches it to the PDF, then either exchanges the Patient Checklist for the one in the BVD 17, or peels off the remaining Box Four sticker, and attaches to the BVD 17 copy.) The hospital pharmacist may elect to convert a non SafeRite R_x to a bar coded R_x 16.

NURSING STATION

- Dispensed drug received at nursing station
- If generic 14 - Box Four sticker attached to PDF

- Drug checked against PDF

WARD

- When administering the R_x to the patient in the ward, the nurse checks that the dispensed drug matches the [illustrated] R_x data included in the Patients Checklist, displayed in the BVD 17

Note: By following the unique and inexpensive BVD 17 drug administering protocol – which takes only a few moments – the nurse is assured that the right drug is given out to the right patient, and that the drug and drug strength complies with the written R_x order.

Patient data, such as condition/illness etc., is contained on the reverse side of the patients' nametag 17. Tags slip out easily for fast reference. In order to accommodate additional R_x's, additional display cards are hung beneath the original card 17. One card will contain recent medication history.

Routing information: ie Fl.5 Rm.123 Bd. C – is displayed on the Patient Checklist portion of the R_x, and accompanies the prescribed drug(s). The physician adds routing data at the time the R_x is written [on the PDA].

Option: The R_x/Checklist is folded back to back and placed in the clear plastic pouch of the BVD 17. Only the illustrated Checklist portion remains visible 17. To read the R_x, the doctor/nurse checks the reverse side of the BVD display card.

In order to facilitate writing the prescription at the patients' bedside, a custom designed case 18 will carry the PDA and printing unit, allowing hands free operation.